

 **Maryland**
Department of Economic &
Employment Development

William Donald Schaefer
Governor

Mark L. Wasserman
Secretary

Board of Appeals
1100 North Eutaw Street, Room 515
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— DECISION —

IN THE MATTER OF THE APPEAL OF:
Pharmakinetics Laboratories

Decision No.: 156-EA-94
Date: November 14, 1994
Exec. Determ. No.: 2157
Employer Account No

ISSUE:

Whether payments to certain individuals constitute covered employment or represent payments to independent contractors and are thereby excluded from unemployment insurance covered wages.

— NOTICE OF RIGHT OF APPEAL TO COURT —

YOU MAY FILE AN APPEAL FROM THIS DECISION IN ACCORDANCE WITH THE LAWS OF MARYLAND. THE APPEAL MAYBE TAKEN IN PERSON OR THROUGH AN ATTORNEY, IN THE CIRCUIT COURT OF THE COUNTY IN MARYLAND IN WHICH YOU DO BUSINESS.

THE PERIOD FOR FILING AN APPEAL TO COURT EXPIRES December 14, 1994

— APPEARANCES —

For the Appellant:

Craig F. Ballew, Esquire
Taryn L. Kunkel, V. P.,
Chief Financial Officer

For the Secretary:

John McGucken, Legal
Legal Counsel

PREAMBLE

The Board of Appeals held a hearing for legal argument only, on the decision of the Special Examiner. The Board recognizes that the employer's company and the business involved here are still in their embryonic stage. Maryland Labor and Employment Article Section 8-205 was originally written when the unique, independent business arrangement discussed herein was not contemplated within the language and spirit of the statute. The statute was written for traditional-type independent contractor arrangements. The Board must apply the law to this new business arrangement between the employer, Pharmakinetics, and the independent contractors -- the "drug-tester volunteers".

FINDINGS OF FACT

The employer performs bio-pharmaceutical services, including clinical evaluations and analytical chemistry services with respect to prescription and non-prescription products (drugs) for the pharmaceutical industry. This is an industry which must operate subject to extensive governmental oversight and regulation. The services that the employer performs provide the data the pharmaceutical companies need to obtain approval from the various governmental agencies to market new products.

To conduct some forms of drug evaluations, the employer uses volunteer test subjects who are selected and reimbursed through the following manner:

1. Initially the volunteers are obtained through referrals and various forms of advertising. These individuals must be drug and alcohol free, have no history of ongoing diseases, and fall within certain weight requirements.
2. The volunteer test subjects are then given (free of charge) a battery of tests to confirm their general health.
3. After satisfying the basic health requirements, the volunteer is advised of upcoming studies to be conducted by the employer. The volunteer drug tester (hereafter known as the "volunteer") is invited to select a study which meets his/her needs, schedule, or other personal criteria. The employer does not require that a volunteer select any study and at no time does the employer assign or direct the volunteer to any particular study.
4. After the volunteer selects a study, he/she is provided with an informed consent contract for participation. This certifies that the volunteer, as a participant of the study, understands the protocol, risks, and conditions of the study. In the consent form is a paragraph which informs the volunteer

of the manner in which he/she shall be reimbursed and acknowledges that he/she is not an employee but an independent, volunteer drug tester.

5. The volunteer is paid a fee for the study based upon the level of perceived risk and the period of time required to eliminate the drug from the volunteer's biological system.

After understanding and signing off the informed consent form, the volunteer is given a dosage of the test drug. After receiving the dose, the volunteer is not required to perform any other work, other than providing blood and/or urine samples at previously agreed to intervals, as per the protocol and requirements of the test. The volunteer remains at the facility for a period of time after receiving the dosage. The exact period of time is determined by the nature of the study being conducted and as required by federal safety regulations. Certain studies require follow-up visits, depending upon the nature of the test.

Volunteers are always free to leave and are paid for the portion of the test which they complete. Leaving or quitting a test after it has started does not disqualify or penalize the volunteer from participation in future tests.

Many volunteers have been involved in multiple studies with the employer and for other companies. Some volunteers have been involved with the business of drug testing for years. Many receive a large portion of their income from the testing of drugs for research companies.

CONCLUSIONS OF LAW

The Labor and Employment Article, §8-205, provides that:

Work that an individual performs under any contract of hire is not covered employment if the Secretary is satisfied that:

(1) the individual who performs the work is free from control and direction over its performance both in fact and under the contract;

(2) the individual customarily is engaged in an independent business or occupation of the same nature as that involved in the work; and

(3) the work is:

(i) outside of the usual course of business of the person for whom the work is performed; or

(ii) performed outside of any place of business of the person for whom the work is performed.

All three prongs of the test must be met in order for the individual performing the work in question to be considered an independent contractor.

Upon review and analysis, the Board concludes that the employer has met the test in this case.

(1) The individual who performs the work is free from control and direction over its performance both in fact and under the contract.

The employer is required to perform a degree of monitoring for safety reasons and to insure the integrity of the test. The monitoring for the safety of the volunteers is established by the FDA and/or an independent, authorized board which establishes the protocol for drug tests. The Board concludes, however, that merely because the employer must follow these guidelines does not, in and of itself, establish an employer-employee relationship under the "control" test as defined in MD LE Article 8-205. Even in traditional independent contractor arrangements the "independent contractor" must conform to certain standards and requirements. For example, when construction management companies hire independent sub-contractors to perform work, they must insure that the OSHA regulations for safety are followed on the job-site. Insuring the integrity of the job and compliance with the law is in no way construed as the general contractor exerting control over the performance of the work.

In traditional general contractor-subcontractor arrangements there is a standard of performance which is established by the end-user (the customer) to outline the responsibilities and structure of the work. These are not controls of the employer. When a general contractor retains the services of an independent sub-contracted, licensed plumber to place plumbing into a house which the contractor is building for a customer, the plumber cannot simply place the pipes anywhere he wishes nor can he just use any materials that he wishes. The contractor has a set of plans (established and approved independently by the customer or his/her agent) which must be followed. The restrictions placed upon the plumber are not by the general contractor, but by the customer. These restrictions and standards do not constitute control by the general contractor. Although the plumber is free to perform his work as he deems proper, he must adhere to the standard set forth in the plans. The sole fact that the plumber must follow the plans does not create an employee-employer relationship. The function of the general contractor is merely to monitor the integrity of the plumber's work in

conformity with the standard set forth by the customer, but not to "control" the performance of the work the plumber performs.

In the case before us, the "plans" are the protocol for the test set forth by an independent source (such as the FDA or another authorized entity) and the customer (a drug company). The employer in this case acts as the general contractor. Its function is to analyze and evaluate data on the absorption of drugs and submit the results to its client. The volunteer is subcontracted for its services - to ingest the drug and supply bodily fluids for analysis whereby the employer can derive its data. The contractor administers the test according to the "plans" and monitors its progress. The volunteer ingests the drug, absorbs it and supplies the fluids at pre-determined intervals. The employer monitors this test to insure that it follows the plan, but cannot sensibly "control" the performance of the work in any manner. For the employer to refrain from all monitoring of the integrity and proper performance of the test would be absurd.

In this case the volunteer is even "more" free from direction than the plumber. The volunteer is free to use his/her time as he/she sees fit. The volunteer has chosen a test which best suits his/her personal needs and schedule. While the volunteer is at the test site, with the exception of providing samples of bodily fluids at pre-established intervals, he/she is performing no other work. A volunteer may choose a test that lasts a few hours to one that lasts a few days. The volunteers choose the amount of time which they wish to devote to a test. If the volunteer does not wish to continue with a test, even after it has begun, he/she may elect to stop, receive a fee for the amount of the test performed, and still be eligible for participation in future tests without penalty. A plumber cannot operate in such a manner.

If the volunteers were employees in the most liberal sense, the employer would control everything from the drug to be tested, which test they were to participate in, for how long they were to participate, and under what conditions they would perform the tests; and, in addition, the employer would disqualify and fire the employee drug tester if he/she did not perform the "duties" necessary to complete the job. In a true employer-employee relationship the employer could select a particular drug tester to perform a particular test, because the employer wanted that particular drug tester for the test, regardless of the tester's emotional feelings and/or reservations about the test. The tester's input would not be relevant. The only criteria that would be of substance would be the employers'.

After the volunteer ingests the drug, it is his/her body which is actually performing the work. The employer cannot logically have control over the performance of the work of the volunteer in this respect. The employer can only monitor for proper administration.

The employer did not exert "control" over the volunteers to establish an employee-employer relationship as defined in LE Article 8-205. The employer has satisfied the requirement of LE, §8-205(1).

(2) The individuals are customarily engaged in an independent occupation of the same nature.

The volunteers who participate in these tests are engaged in the practice of being a drug-tester. They may be involved with multiple studies for multiple companies, providing their services to provide data for pharmaceutical companies' research. They may be involved with the business for two hours or ten years, but they are engaged in the business of providing drug testing services.

The Board finds that the employer has satisfied the requirement of LE, §8-205(2) .

(3) The work is performed outside the usual course of business of the employer.

The employer is in the business of analyzing data and providing the results to the pharmaceutical manufacturers. Testing drugs is merely the part of their business in which they derive their data. The employer contracts the services of volunteers who are in the business of participating in drug testing to provide bodily fluids for analysis after the ingestion of the test drug in a clinical setting, properly monitored for safety and integrity, for a test that the volunteer has unilaterally chosen.

Again, an analogy can be drawn to the subcontractor plumber on a construction job.

The independent sub-contractor, like the volunteer drug tester, is engaged in an occupation independent of the "employer". Although both are an integral part of the process, their function is outside the usual course of business that the employer customarily engages in. In as much as the presence of drug testers is needed in the course of business of the employer in this case, the presence of a sub-contractor plumber is needed and necessary in the course of business of his/her general contractor. The function of the volunteer and the function of the plumber, although necessary

to the business of each "employer", is outside the respective employer's usual course of business.

The usual course of business of the employer is the analysis of data and the reporting of results to the pharmaceutical manufacturer. The usual course of business of the volunteer is providing the service of the ingestion of drugs and the providing of bodily fluids for analysis.

The Board therefore concludes that the third prong of the test has been satisfied.

Therefore, the Board concludes that the three requirements of §8-205 have been met and the employment of the volunteer drug testers is not covered employment, within the meaning of LE, §8-205.

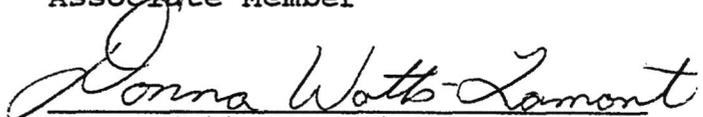
DECISION

The volunteer drug testers are independent contractors and not employees of Pharmakinetics, within the meaning of LE, §8-205.

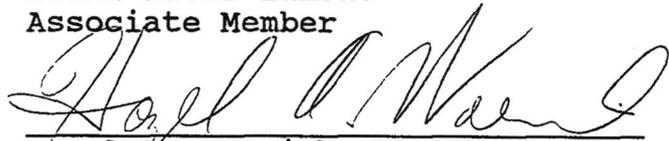
The decision of the Special Examiner is reversed.



Clayton A. Mitchell, Sr.
Associate Member



Donna Watts-Lamont
Associate Member



Hazel A. Warnick
Chairperson

kbm

Date of Hearing: August 17, 1994

COPIES MAILED TO:

EMPLOYER

Craig F. Ballew, Esq.

Jerry Placek, Room 407

John T. McGucken, Legal Counsel, D.E.E.D.

**UNEMPLOYMENT INSURANCE--APPEALS DIVISION
EMPLOYER APPEAL
DECISION**

IN THE MATTER OF THE APPEAL OF:

Parmakinetics Laboratories

EMPLOYER ACCOUNT NUMBER

DETERMINATION NUMBER

0002157

BEFORE THE:

Department of Economic
and Employment Development
Appeals Division
1100 North Eutaw Street
Room 511
Baltimore, MD 21201
(410) 333-5041

June 13, 1994

FOR THE APPELLANT: CRAIG F. BALLEW, ESQUIRE, BREWSTER JONES, PRESIDENT,
TARYN KUNKEL, CHIEF FINANCE OFFICER, RON ADLER, EXPERT WITNESS

FOR THE SECRETARY: JOHN MCGUCKEN, ESQUIRE, JERRY PLACEK, REVIEW
DETERMINATION SUPERVISOR, DANIEL G. CADDEN, CHIEF FIELD AUDITOR,

ISSUE(S)

The issue in this case is whether payments to certain individuals constitute covered employment or represent payments to independent contractors and are thereby excluded from unemployment insurance covered wages.

FINDINGS OF FACT

The record in this case shows that as part of a routine field audit by DEED for 1991-1992, it was determined that Pharmakinetics Laboratories, Inc., had made payment of earnings to a number of persons for whom unemployment insurance taxes totaling some \$89,000 had not been made. As a result, exception was taken to this audit and a review determination (0002157), was made and mailed to the appellant on October 13, 1993. In essence, this determination prepared by the Field Auditor, Daniel G. Cadden, provided that the persons at issue were employees under the Unemployment Insurance Law, rather than independent contractors as urged by Pharmakinetics, Laboratories, Inc., and as such, were subject to the payment of unemployment insurance taxes. From that review determination Pharmakinetics Laboratories, Inc. appeals and this decision results from an administrative hearing held on that appeal.

Phamakinetics Laboratories, Inc. defines itself as a "contract research corporation" which provides data to drug manufacturers necessary for their applications to the US Food and Drug Administration to obtain approval for the sale of the pharmaceutical products in the united states. In pursuit of this

data the appellant is engaged in pre-clinical and clinical (human) testing of various new medications. The portions of this process relevant to the tax issue in this case are the solicitation, engagement and compensation of voluntary test subjects upon who the prospective medications are tested. It appears that many of the test subjects respond to advertisements in the media (appellant's exhibits #1, part J), which solicits test subjects in exchange for varying amounts of compensation commensurate with the physical risks involved and length and/or extent of testing. However, test subjects are also obtained in other ways; there appears to be an informal network of test subjects who solicit the appellant and possibly other organizations, public and private, and there is some word of mouth and personal reference among persons who seek out this type of work. While an estimated 80% test subjects accept some repeat assignments, others may participate in only a single test.

When the appellant and a test subject agreed to a test assignment they entered into an informed consent agreement such as a sample demonstrated in appellant's exhibit #1, part-B. A relatively minor portion of the agreed upon compensation has be-en paid at the start of the test procedure, some compensation later and the bulk at the conclusion. However, this has been altered somewhat in more recent times and as the result of a US Health and Human Services Policy which provides that "the payment should accrue as the study progresses and not be contingent upon completion of the study. " The subjects are free to withdraw from the test and leave the premises at any time, although such an election will almost certainly reduce their total compensation. However, evidence shows that on occasion some have left during the course of the test and accepted their pro-rated payment. Also evidence shows that the appellant's witnesses do not recall any instance in which a test subject participated as an unpaid volunteer. None of the subjects have been known to advertise their own availability as "professional test subjects. "

The test themselves are under the supervisor of an Institutional Review Board composed of professionals in the field who oversee the test operation for both personal safety of the participants and the test results.

At one point persons performing services in this capacity were regarded as employees rather than "independent contractors, as both parties appear to regard their relationship at this time. In fact, the thrust of the appellant's argument is that the participants are independent contractors by agreement and, as such do not expose the appellant to the payment of unemployment insurance taxes. The appellant offers in support of its argument IRS private ruling 9106004, which concerns the case of a medical test subject who was determined, for the purposes of the IRS code, to be an independent contractor. See employer's exhibit #1, part-C. It is noted that this private ruling is marked "This document may not be used or cited as precedent. Section 6110Q(3) of the Internal Revenue Code. "

CONCLUSIONS OF LAW

It is clearly the intent of the appellant and presumably that of the test subjects signing the agreements that the relationship contemplated between the parties is that of an independent contractor. It is a basic principal of common law that parties shall be free to contract among themselves for whatever purpose, provided that the purpose is not prohibited by Law. Here, the purpose, to test drugs, is not prohibited by law, but in fact stringently regulated by the FDA and other governmental bodies. So, in the absence of legislation, the parties should theoretically be free to pursue their lawful business activity under a structure of business organization of their own choosing. That interpretation, however, verges into nostalgia. Government and the legislation which it endlessly generates for a multiplicity of purposes has moved us, for better or worse, far beyond such a simplistic interpretation.

While the parties in this case may see themselves as independent contractors, the UI Law may not, despite their intentions to the contrary. First, the Unemployment Insurance Law presumes, that an employment relationship exists. (See Maryland Code Annotated, Labor and Employment, Sections 8-8-201 and 8-202 Other sections of the Unemployment Insurance Law, Sections 8-205 and 8-206, provide for exceptions from this general presumption. Section 8-205 is the dispositive section of the Law concerned here and it provides: “Work that an individual performs under any contract of hire is not covered employment if the secretary is satisfied that: (1) the individual who performs the work is free from control and direction over its performance both in fact and under the contract; (2) the individual customarily is engaged in an independent business or occupation of the same nature as that involved in the work; and (3) the work is (i) outside of the usual course of business of the person for whom the work is performed; or (ii) performed outside of any place of business of the person for whom the work is performed. ”

This is, quite intentionally, a tough standard to meet because (1) for social purposes the state intends to include as many persons as possible under the protection of the Unemployment Insurance umbrella and (2) for revenue purposes tends to make as many persons as possible subject to UI taxes. In its presumption of employment over contractorship the Legislature made its intention unmistakably clear.

The essence of this case is whether the facts here meet the exception for independent contractors under 8-205. Are the parties involved in the drug tests, “free from control and direction?” The answer is obvious; these are persons testing potentially hazardous drugs and, if for no other reason than their own safety while under the influence of drugs, they must be under the constant control and direction of both the appellant and the IRB. Also, were the test subjects not under the constant control of the appellant the validity of test results provided to its clients could be at question. The argument about the fact that the test subjects are free to leave at any time and that this is an incident of an independent contractor licenseship is spurious. Any employee is always free to leave his employment at any time and not return, thus severing the employment relationship (and many separations from employment occur in exactly that fashion).

Are the drug testers “engaged in an independent business or occupation of the same nature as that involved in the work?” Despite the existence of repeat subjects, the evidence in the record does not

establish that "drug tester" has developed to the level of "an independent business" and that there are persons who regularly offer their metabolic function in the same manner that a plumber or tv repair man offers his services as an independent contractor. The third element of the test contained in 8-205, is that for an independent contractor relationship to be established the work must be "outside the usual course of business of the person for whom the work is performed." The services performed by the drug testers are integral and indispensable to the appellant's usual course of business. Without the drug testers could the appellant serve its client's needs for test data for FDA approval? Clearly it could not. Finally, the services are performed wholly on the premises of the appellant and obviously this requirement is essential to the security of the testers as well as the integrity of the test.

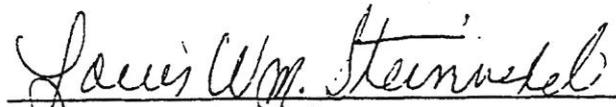
The appellant's argument based on the self stated non-precedent private ruling is interesting but unpersuasive because the ruling represents construction of a set of facts to which the IRS Code and not the Maryland Unemployment Insurance Law, is being applied. In the absence of Maryland Unemployment Insurance Law on this point, the ruling could possibly be more persuasive.

Finally, the appellant contests the method of calculation used to compute the unemployment insurance tax in circumstances where the test subjects are included as employees. While of substantial interest and value to the appellant, this matter is not within the purview of this appeal, and the sole issue presented on appeal is the taxable status of the test subjects.

The appellant's frustration in this matter is understandable, but a remedy for that frustration is not readily available under the Unemployment Insurance Law, as presently constituted. At 8-206, the Law does provide for "specific exceptions from covered employment" and the appellant acting individually or the industry collectively are at liberty to seek inclusion under the provisions of 8-206 through action of the Legislature, as other industries have done.

DECISION

It is held that persons performing the services of test subjects for Phamakinetics Laboratories, Inc. do not meet the three tests set forth in Maryland Code Annotated, Labor and Employment Section 8-205 in order to establish their status as independent contractors. These persons and others similarly situated are held to be employees of Phamakinetics Laboratories, Inc., within the meaning of the Maryland Unemployment Insurance Law, and subject to the payment of Unemployment Insurance Taxes as provided for by Law.



Louis Wm. Steinwedel
Chief Hearing Examiner

Notice of Right of Further Appeal

Any party may request a further appeal **either in person or by mail** which may be filed in any local office of the Department of Economic and Employment Development, or with the Board of Appeals, Room 515, 1100 North Eutaw Street, Baltimore, MD 21201. Your appeal must be filed by **June 28, 1994**

Note: Appeals filed by mail are considered timely on the date of the U.S. Postal Service postmark.

Copies mailed on June 13, 1994 to:

Parmakinetics Laboratories

Jerry Placek,-Room 407

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